UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

JANINE ALI Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01615

PARTIES' JOINT STATEMENT OF UNCONTESTED FACTS

A. The Parties

1. Plaintiff Janine Ali is a resident of the Commonwealth of Virginia.

2. Defendant Eli Lilly and Company is an Indiana corporation with its headquarters in Indianapolis, Indiana.

3. Eli Lilly and Company will be referred to as "Lilly."

4. The Court has subject matter jurisdiction, as well as personal jurisdiction over Lilly.

B. Background

5. Cymbalta is the trade name (or brand name) of a prescription medication, the active ingredient of which is duloxetine hydrochloride. It is also commonly referred to as duloxetine.

6. Cymbalta is a serotonin norepinephrine reuptake inhibitor ("SNRI").

7. Lilly researched, tested, developed, manufactured, labeled, marketed, and sold Cymbalta.

C. Cymbalta Indications and Approvals

8. The U.S. Food and Drug Administration ("FDA") approved Cymbalta in 2004 for the treatment of Major Depressive Disorder ("MDD") and Diabetic Peripheral Neuropathic Pain ("DPNP").

9. The FDA approved Cymbalta in 2007 for the treatment of Generalized Anxiety Disorder ("GAD").

10. The FDA approved Cymbalta in 2008 for the treatment of fibromyalgia.

11. The FDA approved Cymbalta in 2010 for the treatment of chronic musculoskeletal pain.

D. Cymbalta Labels

12. A version of the United States Package Insert ("USPI") for Cymbalta was issued on September 7, 2011, and is numbered PV 7219 AMP.

13. On August 24, 2012, the FDA approved a Medication Guide for Cymbalta, which is numbered PV 7091 AMP.

Dated June 18, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 17th day of June, 2015, I will electronically file the foregoing with the Clerk of the Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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